IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.	Civil Action No. 08-3706-DMC-MF Motion Returnable: January 5, 2009

GSK'S REPLY BRIEF IN FURTHER SUPPORT OF ITS
MOTION FOR JUDGMENT ON THE PLEADINGS

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Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") respectfully submits this reply brief in further support of its motion for judgment on the pleadings under Fed. R. Civ. P. 12(c).

I. SUMMARY OF THE ARGUMENT

The pleadings, which include the contracts in dispute, dispose of Teva's Complaint as a matter of law. Indeed, Teva has not identified any duty set forth in a contract that GSK has breached. As Teva admits: (1) under the contracts "GSK was free to continue selling its product as a ***brand***, and to compete with Teva's product through price reductions in its product" (Opp. at 1)(emphasis added); and (2) GSK only sells ***branded*** lamotrigine products, *i.e.*, LAMICTAL® (D.I. 1 at ¶ 13)(emphasis added). These two undisputed facts confirm that there has been no breach of contract and Teva's Complaint should be dismissed as a matter of law.

In its opposition to GSK's motion for judgment on the pleadings ("Opposition"), Teva argues that GSK's motion is an "attempt to rewrite the License and Supply Agreement." But as Teva's Opposition makes clear, it is Teva, not GSK, that is attempting to rewrite the parties' clear and unambiguous License Agreement.

Teva does this by asking the Court to give the negotiated and defined contract term "Generic Equivalents" a new and completely different meaning. Under the License Agreement as written, LAMICTAL® brand lamotrigine products can never be "Generic Equivalents." Under Teva's proffered rewrite, LAMICTAL® brand lamotrigine products can be "Generic Equivalents" whenever some arbitrary line that Teva has never identified is crossed.

Teva has no support for its wholesale rewrite. Indeed, the law, facts and principles of equity are all aligned against Teva's position. On the law, Pennsylvania law governs and provides that when the terms of a contract are clear and unambiguous, the intent of the parties is to be ascertained from the document itself and a court should look to the four corners of the

document and its express language. *See Hazleton Area School Dist. v. Bosak*, 671 A. 2d 277, 282 (Pa. Cmwlth. 1996). On the facts, Teva has already admitted that the contracts are valid, that GSK is entitled to compete on price, and that GSK only sells LAMICTAL® brand lamotrigine products. On the equities, the result of GSK's actions is that consumers are paying lower prices for lamotrigine products. That is the result of healthy competition, an explicit goal of the contract in dispute. *See* D.I. 11, Exhibit A at ¶ 2.

In an effort to prolong the litigation, Teva argues that one sentence in the License Agreement –"[f]or the avoidance of any doubt, Generic Equivalent shall not include any product sold under GSK's Lamictal® . . . trademark" – is somehow ambiguous. Yet, as discussed in detail below, there is no such ambiguity and no need to prolong the litigation to reference third-party documents to interpret this sentence. *See Panetta v. SAP America, Inc.*, No. 05-4511, 2007 WL 1001889, at *3 (E.D. Pa. March 30, 2007). Indeed, Teva's argument that this sentence somehow ***creates*** ambiguity is belied by the sentence itself. The sentence was added "for the avoidance of any doubt," *i.e.*, to avoid any ambiguity or "doubt" of the kind Teva is trying to create here.

Tellingly, Teva does not assert any alternative meaning for this unequivocal sentence in the contract. Instead, Teva appears to argue that it should just be ignored and the contract rewritten. This argument fails as a matter of law. *See Ardrey Ins. Agency, Inc. v. Ins. Co. of Decatur*, 656 A. 2d 936, 939-40 (Pa. Super. 1995)(finding contracting parties to be bound by the terms of the agreement.)

For all these reasons, as explained in more detail below, GSK respectfully requests that this Court enter judgment for GSK and against Teva on its breach of contract claim.

II. BACKGROUND

The parties do not dispute that this case is based on two 2005 agreements entered into by GSK and Teva in settlement of a patent infringement suit. These agreements gave Teva, *inter alia*, rights to manufacture and sell chewable and non-chewable generic lamotrigine tablet products starting on June 29, 2006 and July 22, 2008, respectively. As admitted by Teva, each of these dates was well before the January 22, 2009 expiration date for GSK's '017 patent and associated exclusivities. (Opp. at 3)

The parties also do not dispute that a contemplated result of these agreements was that there "will be ***pro-competitive generic competition***." (D.I. 11, Exhibit A at ¶ 2) Ironically, this contemplated competition has been accomplished, in part, by the same activity Teva complains of in this case. In essence, Teva complains that too much competition has occurred: Teva's generic lamotrigine products provide competition to GSK's LAMICTAL® brand lamotrigine products and, in turn, competitively priced LAMICTAL® brand lamotrigine products provide competition to Teva's generic lamotrigine products. This competition benefits customers, who now can pay less for their lamotrigine products, branded or generic.

It is further undisputed that the agreements provide ***no restrictions of any kind*** on GSK's sale of its LAMICTAL® brand lamotrigine products. (Opp. at 1) Teva admits that the agreements permitted GSK to sell its LAMICTAL® brand lamotrigine products "***at whatever price it pleases***." (D.I. 16 at 3)

Despite the parties' stated intentions in entering the agreements, and despite Teva's acknowledgement of GSK's right to sell its LAMICTAL® brand lamotrigine products at the price of its choosing, Teva maintains that GSK somehow breached a contractual duty by offering these products at a "discount" and thereby "caused customers to prescribe LAMICTAL®." To make this argument, Teva looks outside the four corners of the License Agreement (which expressly

permits GSK to sell LAMICTAL® brand lamotrigine products at any price it wants) and focuses instead on language in other contracts that GSK has with ***some*** of its customers. That language – which is not part of, not required for, and adds nothing to the interpretation of the License Agreement – essentially identifies for these customers how to record the sales in their systems when a LAMICTAL® brand lamotrigine product is dispensed to a patient because it is price competitively with Teva's generic product.

Reduced to its core elements, Teva's argument is as follows: since GSK prices its LAMICTAL® brand lamotrigine products competitively with Teva's generic lamotrigine products, and since pharmacists will sometimes dispense price-competitive LAMICTAL® when they may have the option to dispense Teva's generic lamotrigine, LAMICTAL® ***must*** be a generic equivalent to Teva's lamotrigine product. There are two fundamental flaws with Teva's argument. First, selling a branded product at a price that competes with a generic product does not turn the branded product into a generic any more than selling a Honda at a price that competes with a Hyundai turns the Honda into a Hyundai. Second, even if a LAMICTAL® brand lamotrigine product could somehow be deemed generic lamotrigine in some general economic discussion, the definition of Generic Equivalents in the License Agreement specifically excludes this possibility.

As acknowledged by Teva, the term "Generic Equivalent" is defined by the License Agreement as follows:

> "Generic Equivalent" shall mean, on a product by product basis, any (i) FDA approved (for the avoidance of doubt, not a tentative approval) prescription generic Lamotrigine tablet product (in either 25mg, 100mg, 150mg or 200mg strength, as the case may be) for human use that is A Rated to, or supplied or manufactured by or for GSK (or its Affiliates) under NDA No. 20-241 for sale in the Territory as a generic equivalent to, the applicable 25mg, 100mg, 150mg, or 200mg strength of GSK's Lamictal® (Lamotrigine) tablets approved under GSK's NDA No. 20-241, and (ii) FDA approved (for the avoidance of doubt, not a

> tentative approval) prescription generic Lamotrigine chewable dispersible tablet product (in either 5mg or 25mg strength, as the case may be) for human use that is A Rated to, or supplied or manufactured by or for GSK (or its Affiliates) under NDA No. 20-764 for sale in the Territory as a generic equivalent to, the applicable 5mg or 25mg strength of GSK's Lamictal® (Lamotrigine) chewable dispersible tablets approved under GSK's NDA No. 20-764. ***For the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its Affiliates)***

(D.I. 11, Exhibit B at § 1.1; Opp. at 4) (emphasis added) Given this definition, it is beyond legitimate dispute that GSK's LAMICTAL® brand lamotrigine products are explicitly excluded from the scope of "Generic Equivalents."

Teva admits that this language was aimed at prohibiting GSK from marketing an "authorized generic." (Opp. at 5) And Teva further admits that GSK is not marketing an "authorized generic" or any generic at all. (Opp. at 5-6) Rather, GSK is selling the same product it was selling at the time of the agreement, *i.e.*, the branded product, LAMICTAL®. GSK has not changed the brand's packaging, product appearance, or anything else that would render this branded product a generic. Instead, GSK has simply lowered the price, an action that was expressly authorized by the License Agreement and that Teva admits GSK was free to take. GSK has included these lower prices in contracts with its vendors. And, in some instances, it has included a provision in those third-party contracts that discusses how the sales of the reduced-price LAMICTAL® brand lamotrigine products can be recorded in the customer's dispensing software.

III. JUDGMENT SHOULD BE ENTERED ON THE PLEADINGS FOR GSK AND AGAINST TEVA

The parties agree that courts apply the same standard on a Fed. R. Civ. P. 12(c) motion for judgment on the pleadings as on a motion to dismiss pursuant to Rule 12(b)(6). (Opp. at 7) In deciding a Rule 12(c) motion, as on a Rule 12(b)(6) motion, courts accept all factual

allegations in the Complaint as true and view them in the light most favorable to the plaintiff. Teva and GSK cite a number of cases confirming this statement of law. Teva, however, ignores the case law explaining that courts need not credit bald assertions or legal conclusions improperly alleged in the complaint. *See e.g., Cryofab, Inc. v. Precision Medical, Inc.*, No. 08-1236 (JLL), 2008 WL 2705007, at *1 (D.N.J. July 08, 2008) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F. 3d 1410, 1429 (3d Cir. 1997)). Teva also ignores the case law confirming that courts need not accept factual assertions that are contradicted by averments in the pleadings and/or exhibits attached thereto. *See, e.g., Northern Indiana Gun & Outdoor Shows, Inc. v. City of South Bend*, 163 F. 3d 449, 452 (7th Cir. 1998); *see also Graue Mill Dev. Corp. v. Colonial Bank & Trust Co. of Chicago*, 927 F. 2d 988, 991 (7th Cir. 1991) (stating that "[w]here the allegations of a pleading are inconsistent with the terms of a written contract attached as an exhibit, the terms of the latter, fairly construed, must prevail over the averments differing therefrom").

As explained in GSK's opening brief, a breach of contract claim in Pennsylvania must be established by demonstrating the following three elements: "'(1) the existence of a contract, including its essential terms, (2) a breach of duty imposed by the contract, and (3) resultant damages.'" *Gazarov*, 80 Fed. Appx. at 206 (quoting *Williams v. Nationwide Mut. Ins.* Co., 750 A. 2d 881, 884 (Pa. Super. Ct. 2000)). The parties have agreed that the Settlement Agreement and the License Agreement are valid, binding contracts. (*See* D.I. 1 at ¶ 31; D.I. 11 at ¶ 31) The only issue in dispute on this motion is whether GSK breached a duty imposed by those contracts. Specifically, the only issue in dispute is whether GSK has sold a Generic Equivalent to its LAMICTAL® brand lamotrigine products in breach of its contract with Teva.

Significantly, it is undisputed that GSK does not sell a "Generic Equivalent" as that term is defined in the contract. (Opp. at 1) This fact alone disposes of Teva's Complaint. *See Gazarov*, 80 Fed. Appx. at 206 (stating there must be "a breach of duty imposed by the contract" for a successful breach of contract claim). The Court need not consider any other aspect of Teva's Opposition to grant judgment to GSK. *See Panetta v. SAP America, Inc.*, No. 05-4511, 2007 WL 1001889, at *3 (E.D. Pa. March 30, 2007) (stating that unambiguous contracts are interpreted by the court as a matter of law). And, in any event, the parties agree to the relevant facts. Under the contracts, "GSK was free to continue selling its product as a ***brand***, and to compete with Teva's product through price reductions in its product," and GSK only sells ***branded*** lamotrigine products, *i.e.*, LAMICTAL®. *See* Opp. at 1; *see also* D.I. 1 at 13.

Admitting these facts, Teva is left to argue that the Court should change the parties' agreed-to definition of "Generic Equivalents" by adding price restrictions and/or pharmacy reimbursement codes to the agreed definition. This would be improper. *See Panetta*, 2007 WL 1001889, at *3 ("When the terms of a contract are clear and unambiguous, the intent of the parties is to be ascertained from the document itself.").[1]

Teva improperly relies on certain DAW ("Dispense as Written") codes to argue that GSK has somehow breached the License Agreement. The License Agreement, however, does not

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[1] Teva relies on *Mellon Bank* (fn. 4) and asks this Court to consider "industry practices" in interpreting the phrase "Generic Equivalents." But, *Mellon Bank* is inapposite. In *Mellon Bank*, the court only considered industry practice after determining there was ambiguity, which it defined as "[i]ntellectual uncertainty; . . . the condition of admitting two or more meanings, of being understood in more than one way, or referring to two or more things at the same time." *Mellon Bank, N.A. v. Aetna us. Credit, Inc.*, 619 F.2d 1001, 1011 (3d Cir. 1980) Here, there is no second reasonable interpretation of "Generic Equivalents" proposed by Teva. Moreover, as discussed above, even if the Court were to consider this phrase ambiguous, "industry practices" would not dictate a definition different from the one explicitly included in the contract, *i.e.*, "Generic Equivalents" does not include LAMICTAL® brand lamotrigine products.

refer to these codes. Moreover, as noted in GSK's opening brief, the DAW codes are consistent with the parties' agreed-to definition of "Generic Equivalents," as they ***distinguish*** between "generics" and branded drugs. A branded product, such as LAMICTAL®, cannot, by definition, be a generic. A brand is the opposite of a generic. (Merriam-Webster's Collegiate Dictionary, 11th Ed. 2004, Ex. C; s*ee also* Webster's II New College Dictionary, 3d Ed. 2005, Ex. D) (stating the definition of "generic" is "being or having a nonproprietary name."). A branded drug can be, and often is, reimbursed in the same way as a generic when priced competitively with a generic. (*See, e.g.*, D.I. 1 at ¶ 26) But no dispensing or reimbursement code could render GSK's LAMICTAL® brand lamotrigine products "generic," much less "Generic Equivalents" under the Agreements.

Teva argues that the undefined term "generic equivalents" is "easily understood, common words" which should be "understood in their ordinary meaning" to include the branded product. (Opp. at 9) This makes no sense. First, if the parties agreed that "generic equivalents" was easily understood, there would have been no need to define the term "Generic Equivalents" in the contract. Second, Teva ignores that the words "generic equivalent," when used within the parties' agreed-to definition of "Generic Equivalents," distinguish from the branded product, *i.e.*, the branded product is what the "generic" is "equivalent" to. *See* Exhibit B at Section 1.1. As a result, "Generic Equivalents" does not and cannot include LAMICTAL® brand lamotrigine products, either as explicitly defined in the contract, or as "easily understood, common words."

Teva retreats to the argument that the definition of "Generic Equivalents" is somehow ambiguous and was drafted by GSK. As a result, Teva argues that this sentence should be construed against GSK. (Opp. at 2) Teva provides no basis for this statement. Teva's Complaint contains no allegation as to who drafted this provision of the contract. Instead, Teva

refers in its brief to "parol evidence" it allegedly ***will*** offer. *Id.* This allusion to possible, future evidence, which is contradicted by the contract itself, cannot save Teva's Complaint. As noted above, a motion for judgment on the pleadings follows similar standards as those for a motion to dismiss under Fed. R. Civ. P. 12 (b)(6). "When reviewing a motion to dismiss under Rule 12(b)(6), the District Court considers whether the plaintiff is entitled to offer evidence to support the allegations in the complaint. Indeed, the purpose of Rule 12(b)(6) is to 'streamline[] litigation by dispensing with needless discovery and fact finding.'" *See Clark v. Vernon,* 228 Fed. Appx. 128, 132-3 (3d Cir. 2007) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F. 3d 1410, 1429 (3d Cir. 1997)) Teva is not entitled to prolong litigation to try to contradict express contract language it negotiated and adopted. Judgment on the pleadings should be granted accordingly.

Significantly, it is undisputed that Teva was represented by competent counsel during the drafting and negotiating of the contract in dispute. In fact, the Settlement Agreement states "this Settlement Agreement is the product of negotiation and preparation by the Parties and their respective attorneys. The Parties, therefore, expressly acknowledge and agree that this Settlement Agreement shall be deemed jointly prepared and drafted by all of the Parties, and their attorneys, and shall be construed accordingly." (D.I. 11, Exhibit A at ¶ 4) And as Teva agrees, the "language of the License & Supply Agreement . . . speak[s] for itself." (D.I. 16 at ¶ 12)

Teva admits that the final sentence of the definition of "Generic Equivalents," – "[f]or the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its Affiliates)" – was added as a clarification. (D.I. 10 at 2) There is no dispute that it existed in the

contract signed by Teva and formed part of the bargain. Teva should not be allowed years later to ask Court to rewrite the contract and remove this sentence. *See Ardrey Ins. Agency*, 656 A.2d at 939-40 ("A party's failure to anticipate all possible repercussions of a bargained for contract, is insufficient to render the contract invalid.") Teva's argument that this sentence somehow creates an ambiguity is belied by the sentence itself. The sentence was expressly added to ***avoid*** any ambiguity as to the meaning of the term "Generic Equivalents." No matter how the rest of the definition read, the parties agreed that there was to be ***no doubt*** that the term ***did not include any Product sold under GSK's Lamictal® or Lamictal XR trademark***.

Teva's reliance on *Ford Motor Co.* (Opp. at 16) is misplaced. In *Ford Motor* , the motion to dismiss was denied after the Court determined that there was more than one plausible interpretation of the ambiguous contract term. *Ford Motor Co. v. Edgewood Props.*, Nos. 06-1278, 06-4266, 2008 WL 4559770 (D.N.J. May 20, 2008) Here, by contrast, there is only one plausible interpretation of the term "Generic Equivalents." Indeed, the parties defined "Generic Equivalents" with the final sentence to avoid any possible ambiguity, *i.e.*, "for avoidance of doubt." Teva cannot now change the deal it made with GSK. *See Ardrey Ins. Agency*, 656 A.2d at 939-40.

In sum, as Teva admits, the License Agreement only prohibits the sale by GSK of "Generic Equivalents," a term that is specifically defined. GSK has not sold, and Teva has not claimed GSK has sold, any "Generic Equivalent" as that term is specifically defined in the contract. GSK sells only LAMICTAL® brand lamotrigine products, which are expressly excluded from the definition of "Generic Equivalents." (D.I. 11, Exhibit B at § 1.1) These facts confirm that Teva's claim is meritless as a matter of law. Judgment on the pleadings is therefore appropriate for the parties and necessary so the Court can focus on other cases in actual dispute.

IV. CONCLUSION

For all the foregoing reasons, GSK respectfully requests that the Court enter judgment for GSK and against Teva on its breach of contract claim.

Dated: December 29, 2008

Respectfully submitted,

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